purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) [Reserved]

(d) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

§ 74.1707 D&C Yellow No. 7.

(a) *Identity.* (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.
Matter insoluble in alkaline water, not more than 0.5 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-2,4-(Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 94 percent.

(c) *Uses and restrictions.* D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1707a Ext. D&C Yellow No. 7.

(a) *Identity.* (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Ext. D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
1-Naphthol, not more than 0.2 percent.
2,4-Dinitro-1-naphthol, not more than 0.03 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1708 D&C Yellow No. 8.

(a) *Identity.* (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter

for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 8 shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in alkaline water, not more than 0.3 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(2,4-Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Yellow No. 8 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1710 D&C Yellow No. 10.

(a) *Identity.* (1) The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004–92–0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

(2) Color additive mixtures made with D&C Yellow No. 10 for drug use may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Yellow No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in both water and chloroform, not more than 0.2 percent.
Total sulfonated quinaldines, sodium salts, not more than 0.2 percent.
Total sulfonated phthalic acids, sodium salts, not more than 0.2 percent.
2-(2-Quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 4 parts per million.
Sum of sodium salts of the monosulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not less than 75 percent.
Sum of sodium salts of the disulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 15 percent.
2-(2,3-Dihydro-1,3-dioxo-1*H*-indene-2-yl)-6, 8-quinolinedisulfonic acid, disodium salt, not more than 3 percent.
Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39219, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]